

Remarks

This paper is responsive to the Office Action mailed January 10, 2008. This paper is filed with a request for a three-month extension of time pursuant to 37 C.F.R. § 1.136(a) and a Request for Continued Examination.

In the Action, the Office rejected claims 1-6 and 30-62.

Claim Rejections – 35 U.S.C. § 103(a)

The Examiner has rejected claims 1-3, 5, and 6 under 35 U.S.C. § 103(a), as being unpatentable over Andrianov *et al.* (USPN 5,529,777) in view of Sokoll *et al.* (USPN 6,228,423 B1). Applicants respectfully traverse this rejection.

The guidelines for determining obviousness under 35 U.S.C. § 103 are found in M.P.E.P. § 2141. The framework for an objective analysis in determining obviousness under 35 U.S.C. § 103 is stated in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The required factual inquiries announced by the United States Supreme Court are as follows:

- (A) determining the scope and content of the prior art;
- (B) ascertaining the differences between the claimed invention and the prior art; and
- (C) resolving the level of ordinary skill in the art.

An Examiner must articulate these findings of fact to support an obviousness rejection under 35 U.S.C. § 103. Furthermore, the Examiner must establish “an apparent reason to combine . . . known elements” and must expressly articulate the underlying analysis supporting a proffered “apparent reason.” *KSR Int’l. Co. v. Teleflex Inc.*, No. 04-1350, slip op. at 4 (U.S. April 30, 2007). Applicants respectfully submit that the Examiner has not met the requirements for establishing a *prima facie* case of obviousness.

In the instant case, the Examiner lists various teachings found in Andrianov, and states that Andrianov does not teach the basic additive of magnesium carbonate. The Examiner then

refers to Sokoll as providing magnesium carbonate in a way that would make it *prima facie* obvious to one of ordinary skill in the art to modify Andrianov to accommodate the disclosure of magnesium carbonate in the formulation disclosed in Sokoll. The only support offered for this assertion is that it would have been obvious to combine both references due to their relative similarity in scope of invention.

However, *KSR* expressly instructs that it remains legally insufficient to conclude that a claim is obvious just because each feature of a claim can be independently shown in the cited art. The Court quoting *In re Kahn*, 441 F.3d 977 (Fed. Cir. 2006), stated that “[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR*, No. 04–1350, slip op. at 14. Exemplary rationales that may support a conclusion of obviousness can be found at M.P.E.P. § 2141 part III. The Examiner’s assertion that the relative similarity in scope of invention renders obvious claims 1-3, 5, and 6 is not among any of the exemplary rationales listing in M.P.E.P. § 2141 part III. Also, the Examiner provides no guidance as to resolving the level of ordinary skill in the art as required to make a *prima facie* case of obviousness.

Furthermore, the Examiner identifies that Andrianov teaches a method to elicit an immunogenic response incorporating PLGA, then states one of ordinary skill in the art would further look to Sokoll for guidance on eliciting an immune response. Applicant respectfully asserts that one of ordinary skill in the art would not look to Sokoll for further guidance on eliciting an immunogenic response since Andrianov poses no reason to look anywhere else for guidance as to how one would elicit an immunogenic response. Andrianov provides the problem relied on by the Examiner, but also provides solutions to that problem. The Supreme Court has reaffirmed that “[a] factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of argument reliant upon *ex post* reasoning.” *KSR*, No. 04–1350, slip op. at 17. *See also Graham*, 383 U.S. at 36. A person of ordinary skill in the art at the time of the invention would not have reasonably looked to Sokoll to solve a problem already solved by Andrianov. Therefore, Applicants respectfully submit that the Examiner has impermissibly used the instant claims as a guide or roadmap in formulating the rejection. Applicants respectfully

submit that all of the pending claims are in condition for allowance, and request reconsideration by the Examiner.

The Examiner has also rejected claim 4 under 35 U.S.C. § 103(a), as being unpatentable over Schoch, E.P. (Industrial and Engineering Chemistry; Direct Titrometric Methods for Magnesium, Calcium, and Sulfate Ions and Their Application in Water Analysis; 1926, Vol. 19, No. 1, page 112) and CHEMTUTOR, LLC (Acids and Bases; The 5% Rule, Copyright 1997, page 17), in view of Lenntech (Magnesium (Mg) and water; Chemical Properties, Health and Environmental Effects; Copyright 1998, page 1). Applicants respectfully traverse this rejection.

The Examiner has again provided a list of various teachings provided by the cited references, and concluded that the teachings of properties and characteristics of magnesium carbonate in Lenntech would be the motivation to further combine the references of Schoch, CHEMTUTOR, and Lenntech. Applicants again respectfully point out that it remains legally insufficient to conclude that a claim is obvious just because each feature of a claim can be independently shown in the cited art. One of ordinary skill in the art reading Schoch, CHEMTUTOR, and Lenntech would have absolutely no reason to apply those teachings to a method of enhancing an immunogenic response in a mammalian subject since none of those references are directed to immunogenicity. Without the hindsight bias of the instant claims, one of ordinary skill reading the three cited references would indeed have a full understanding of the properties of magnesium compounds and may score well on a general chemistry examination relating to properties of magnesium, but they would be no closer to applying those teachings to achieve an enhanced immunogenic response in a mammalian subject than they would be to turning magnesium into gold. Applicants respectfully submit claim 4 is not obvious in light of Schoch, CHEMTUTOR, and Lenntech as none of the references read individually or together provide all the elements of claim 4 (which depends from claim 2, which depends from claim 30, which depends from claim 1), and one of ordinary skill would have no ability to derive the claimed method upon considering the three references. Reconsideration of the rejection is respectfully requested.

The Examiner has rejected claims 30-62 under 35 U.S.C. § 103(a), as being unpatentable over Wright *et al.* (USPN 6,379,704 B2) and Thanavala *et al.* (Affinity, cross-reactivity and biological effectiveness of rabbit antibodies against a synthetic 37 amino acid C-terminal peptide of human chorionic gonadotropin, Clin. Exp. Immunol. (1980) 39, 112-118), in view of Setterstrom *et al.* (USPN 6,309,669 B1). Applicants respectfully traverse this rejection.

Applicants again respectfully reiterate that the Examiner has not met the requirements for a *prima facie* case of obviousness. The Examiner uses Wright to establish a method of preparing microparticles having a selected polymer molecular weight, but notes that Wright does not teach human chorionic gonadotropin or carboxyl terminal peptides. It is then asserted that Thanavala teaches human chorionic gonadotropin and carboxyl terminal peptides, however neither Wright or Thanavala teach adjuvants. Then it is asserted that Setterstrom teach adjuvants. These three references combined in such a manner would preclude the patentability of ANY newly discovered microparticle vaccine, since ANY microparticle vaccine would comprise microparticles, an antigen, and adjuvant. If microparticle vaccines are in fact obvious, we would see many of them on the market or in clinical trials. Yet we do not observe such a phenomena. Again, the Examiner has impermissibly used the instant claims as a guide or roadmap in formulating the rejection. Applicants respectfully assert that the fact one of ordinary skill in the art may be capable of putting together multiple elements upon reading a claim does not render a claim obvious. Of course one of ordinary skill in the art would have the capability of reading a claim and combining multiple references using the claims as a guideline to arrive at a claimed invention, however this is not the standard for obviousness. There is nothing in any of the three cited references that when read together would lead one of ordinary skill in the art to arrive at the method of the instant claims. Furthermore, the Examiner has again failed to resolve the level of skill in the art. Therefore, since the three requirements of the *Graham* test have not been satisfied, the Examiner has not made a *prima facie* case of obviousness. Applicants respectfully submit that the instant claims are patentable and request reconsideration of the rejection.

In the event the Commissioner should decide that any additional fee or fee deficiency is due, the Commissioner is hereby authorized to charge any and all fees incurred as a result of entering or considering this document to deposit account number 03-0172.

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Response to Final Office Action

Respectfully submitted,

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